

PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to system.

1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:

Department of Defense (DoD) Birth and Infant Health Research (BIHR) Program

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

04/22/2025

Bureau of Medicine and Surgery (BUMED)

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: (Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)

From members of the general public From Federal employees

from both members of the general public and Federal employees Not Collected (if checked proceed to Section 4)

b. The PII is in a: (Check one.)

New DoD Information System New Electronic Collection

Existing DoD Information System Existing Electronic Collection

Significantly Modified DoD Information System

c. Describe the purpose of this DoD information system or electronic collection and describe the types of personal information about individuals collected in the system.

The Assistant Secretary of Defense for Health Affairs directed the establishment of a birth defects registry for military families in 1998. Tasked with accomplishing this mission, the Naval Health Research Center (NHRC) established the Department of Defense (DoD) Birth and Infant Health Research (BIHR) program to conduct surveillance for reproductive health outcomes. The primary objective of the BIHR program is to conduct surveillance for birth defects among DoD health care beneficiaries. Secondary objectives are to monitor other indicators of infant health, such as pre-term birth, birth weight, growth problems in utero or in infancy, and neoplasms in infancy, as well as assess pregnancy and other maternal outcomes, including pregnancy losses, among DoD medical beneficiaries. The BIHR data is also used for DoD/DHA funded research.

BIHR system is a network SAS database with relational capabilities managed by SAS software, hosted on-premises type servers within the NHRC MedCOI Enclave boundary with multiple end users. The data collected is used to respond to inquiries from military leadership, military medical providers, policy makers, and to conduct research with the ultimate aim of ensuring the welfare of children born to military families which impacts readiness. The BIHR program's mission has expanded to enable proactive assessments of maternal and pregnancy outcomes because they are intrinsically linked to infant health outcomes and are of interest to military service members and leadership.

Data for the BIHR program is obtained from existing DoD information systems and collections. The Personally Identifiable Information (PII) that is collected includes Social Security Number (SSN); DoD identification number; demographic data; Military Treatment Facility (MTF) and installation location data, military personnel records; physical readiness data; health care data maintained by the Military Health System (MHS); mortality data; self-reported survey data, as available; and state birth certificate data, as available.

The BIHR data is maintained by the Naval Health Research Center (NHRC) on NHRC owned servers; supported by the NHRC IT Department and managed by the Military Population Health Directorate.

d. Why is the PII collected and/or what is the intended use of the PII? (e.g., verification, identification, authentication, data matching, mission-related use, administrative use)

The PII is collected for data matching, verification, and the intended use is for mission-related purposes.

e. Do individuals have the opportunity to object to the collection of their PII? Yes No

(1) If "Yes," describe the method by which individuals can object to the collection of PII.

(2) If "No," state the reason why individuals cannot object to the collection of PII.

The BIHR program is a large population-based electronic data surveillance study that obtains PII from existing DoD information systems

and collections. As BIHR is not the initial point of data collection, individuals do not have the opportunity to object to the collection of their PII.

f. Do individuals have the opportunity to consent to the specific uses of their PII? Yes No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

Individuals do not have the opportunity to provide consent to the collection and use of their PII as BIHR is not the initial point of collection of data.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. (Check as appropriate and provide the actual wording.)

Privacy Act Statement Privacy Advisory Not Applicable

The BIHR system does not collect personally identifiable information directly from individuals; however, the primary source systems have applicable System of Record Notices. The applicable SORNs for this collection are under the authorities of Department of Navy's DoD Birth Defects Registry, N06150-4 (June 16, 2003, 68 FR 35657) and Defense Health Agency's Military Health Information System, EDHA 07 (June 15, 2020; 85 FR 36190).

The following Privacy Act Statement is utilized by EDHA-07:

1. AUTHORITY FOR COLLECTION OF INFORMATION INCLUDING SOCIAL SECURITY NUMBER (SSN):

10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. Chapter 55, Medical and Dental Care; 42 U.S.C. Chapter 32, Third Party Liability for Hospital and Medical Care; 32 CFR Part 199, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); DoDI 6055.05, Occupational and Environmental Health (OEH); and E.O. 9397 (SSN), as amended.

2. PRINCIPAL PURPOSES FOR WHICH INFORMATION IS INTENDED TO BE USED:

Information may be collected from you to provide and document your medical care; determine your eligibility for benefits and entitlements; adjudicate claims; determine whether a third party is responsible for the cost of Military Health System (MHS) provided healthcare and recover that cost; evaluate your fitness for duty and medical concerns which may have resulted from an occupational or environmental hazard; evaluate the MHS and its programs; and perform administrative tasks related to MHS operations and personnel readiness.

3. ROUTINE USES:

Information in your records may be disclosed to:

Private physicians and Federal agencies, including the Department of Veterans Affairs, Health and Human Services, and Homeland Security (with regard to members of the Coast Guard), in connection with your medical care;

Government agencies to determine your eligibility for benefits and entitlements;

Government and non-government third parties to recover the cost of MHS provided care;

Public health authorities to document and review occupational and environmental exposure data; and

Government and non-government organizations to perform DoD-approved research.

Information in your records may be used for other lawful reasons which may include teaching, compiling statistical data, and evaluating the care rendered. Use and disclosure of your records outside of DoD may also occur in accordance with 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, which incorporates the DoD Blanket Routine Uses published at:

<http://dpcl.dod.mil/privacy/SORNsIndex/BlanketRoutineUses.aspx>

Any protected health information (PHI) in your records may be used and disclosed generally as permitted by the HIPAA Privacy Rule (45 CFR Parts 160 and 164), as implemented within DoD by DoD 6025.18-R. Permitted uses and disclosures of PHI include, but are not limited to, treatment, payment, and healthcare operations.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:

Voluntary. If you choose not to provide the requested information, comprehensive health care services may not be possible, you may experience administrative delays, and you may be rejected for service or an assignment. However, care will not be denied. This all inclusive Privacy Act Statement will apply to all requests for personal information made by MHS health care treatment personnel or for medical/dental treatment purposes and is intended to become a permanent part of your health care record.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? (Check all that apply)

Within the DoD Component

Specify.

Military Treatment Facility (MTF) providers within the Defense Health Agency for specific IRB approved projects.

Other DoD Components (i.e. Army, Navy, Air Force)

Specify.

PII might be shared for specific IRB approved projects with Department of Navy researchers; BUMED Headquarters; IRB approved projects with providers and/or researchers within the U.S. Air Force, U.S. Army, U.S. Space Force,

Specify.	and researchers at Uniformed Services University of the Health Sciences.	<input checked="" type="checkbox"/> Other Federal Agencies (i.e. Veteran's Affairs, Energy, State)								
Specify.	Department of Homeland Security/Coast Guard.	<input type="checkbox"/> State and Local Agencies								
Specify.		<input checked="" type="checkbox"/> Contractor (Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)								
Specify.	The Leidos contract includes appropriate FAR privacy clauses 52.224-1, Privacy Act Notification and 52.224-2, Privacy Act and appropriate DoD Cybersecurity FAR Clauses. The contract Performance Work Statement (PWS) has Business Associate Agreement (BAA) language subjecting the vendor to the HIPAA Privacy, Security and Breach Notification Rules.	<input type="checkbox"/> Other (e.g., commercial providers, colleges).								
Specify.	Commercial industry partners, such as pharmaceutical companies, for IRB approved projects. PII is also shared for IRB approved projects with non-DoD universities and the Uniformed Services University of the Health Sciences (USUHS).									
<p>i. Source of the PII collected is: (Check all that apply and list all information systems if applicable)</p> <table> <tr> <td><input type="checkbox"/> Individuals</td> <td><input checked="" type="checkbox"/> Databases</td> </tr> <tr> <td><input checked="" type="checkbox"/> Existing DoD Information Systems</td> <td><input type="checkbox"/> Commercial Systems</td> </tr> <tr> <td><input checked="" type="checkbox"/> Other Federal Information Systems</td> <td></td> </tr> </table>			<input type="checkbox"/> Individuals	<input checked="" type="checkbox"/> Databases	<input checked="" type="checkbox"/> Existing DoD Information Systems	<input type="checkbox"/> Commercial Systems	<input checked="" type="checkbox"/> Other Federal Information Systems			
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<p>PII/PHI are collected from existing DoD information systems, from DoD collections as available (e.g. Millennium Cohort Study), other Federal information systems or databases, and state birth certificates. Some data are collected routinely to build the BIHR database, and other collections are obtained for specific projects (i.e., not routinely collected). See the attached BIHR data flow diagram for more details. DoD source systems include:</p> <ol style="list-style-type: none"> 1. Defense Manpower Data Center (DMDC) <ol style="list-style-type: none"> a. Personnel / Career Data b. Demographic Data c. Deployment Data 2. Military Health System (MHS) Information Platform (MIP) / Defense Health Agency (DHA) <ol style="list-style-type: none"> a. MHS Data Repository (MDR) b. Defense Medical Surveillance System (DMSS) c. Immunization Data d. DoD Serum Repository 3. Electronic Health Records <ol style="list-style-type: none"> a. MHS GENESIS b. Armed Forces Health Longitudinal Technology Application (AHLTA) c. Composite Health Care System (CHCS) d. Clinical Information System (CIS)/Essentris 4. In-house, NHRC Servers <ol style="list-style-type: none"> a. Millennium Cohort Study b. Millennium Cohort Family Study c. Physical Readiness Information Management System (PRIMS) 5. DoD and Veterans Affairs (VA) Suicide Data Repository (SDR) 6. Family Advocacy Program data 7. Non-DHA sources: <ol style="list-style-type: none"> a. U.S. Health and Human Services' Vaccine Adverse Events Reporting System (VAERS) b. State Birth certificate 										
<p>j. How will the information be collected? (Check all that apply and list all Official Form Numbers if applicable)</p> <table> <tr> <td><input type="checkbox"/> E-mail</td> <td><input type="checkbox"/> Official Form (Enter Form Number(s) in the box below)</td> </tr> <tr> <td><input type="checkbox"/> In-Person Contact</td> <td><input type="checkbox"/> Paper</td> </tr> <tr> <td><input type="checkbox"/> Fax</td> <td><input type="checkbox"/> Telephone Interview</td> </tr> <tr> <td><input type="checkbox"/> Information Sharing - System to System</td> <td><input type="checkbox"/> Website/E-Form</td> </tr> </table>			<input type="checkbox"/> E-mail	<input type="checkbox"/> Official Form (Enter Form Number(s) in the box below)	<input type="checkbox"/> In-Person Contact	<input type="checkbox"/> Paper	<input type="checkbox"/> Fax	<input type="checkbox"/> Telephone Interview	<input type="checkbox"/> Information Sharing - System to System	<input type="checkbox"/> Website/E-Form
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Other (If Other, enter the information in the box below)

Electronic from existing DoD information systems, other federal information systems, and non-federal data collections.

k. Does this DoD Information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

Yes No

If "Yes," enter SORN System Identifier N06150-4; EDHA-07

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or <http://dpcld.defense.gov/> Privacy/SORNS/ or

If a SORN has not yet been published in the Federal Register, enter date of submission for approval to Defense Privacy, Civil Liberties, and Transparency Division (DPCLTD). Consult the DoD Component Privacy Office for this date.

If "No," explain why the SORN is not required in accordance with DoD Regulation 5400.11-R: Department of Defense Privacy Program.

I. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?

(1) NARA Job Number or General Records Schedule Authority.

DAA-NU-2015-0006-0003; DAA-NU-2015-0006-0016

(2) If pending, provide the date the SF-115 was submitted to NARA.

(3) Retention Instructions.

DAA-NU-2015-0006-0003- PERMANENT: Cutoff at end of calendar year. Transfer to the National Archives 25 years after cutoff;

DAA-NU-2015-0006-0016- TEMPORARY: Cutoff at end of calendar year. Destroy 10 year(s) after cutoff

m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statute or Executive Order.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.

(2) If a SORN does not apply, cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply).

(a) Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If direct statutory authority or an Executive Order does not exist, indirect statutory authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

(c) If direct or indirect authority does not exist, DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component must be identified.

EDHA-07, Military Health Information System (Current SORN);

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter Ch. 55, Medical and Dental Care; 10 U.S.C. 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 U.S.C. 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 U.S.C. 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 U.S.C. 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 42 U.S.C. 290dd, Substance Abuse Among Government and Other Employees; 42 U.S.C. 290dd-2, Confidentiality Of Records; 42 U.S.C. 42 U.S.C. Ch. 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of Defense (DoD) Instruction 6015.23, Foreign Military Personnel Care and Uniform Business Offices in Military Treatment Facilities (MTFS); DoD 6025.18-R, DoD Health Information Privacy Regulation; and E.O. 9397 (SSN).

N06150-4, DoD Birth and Infant Health Research (BIHR) program SORN (DoD Birth Defects)

10 U.S.C. 131, Office of the Secretary of Defense; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. 2358, Research and Development Projects; E.O. 9397 (SSN); and OASD/HA Policy for National Surveillance for Birth Defects Among

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (OMB) Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information. This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

Yes No Pending

(1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.

(2) If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, "DoD Information Collections Manual: Procedures for DoD Public Information Collections."

(3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected within this system is for the diagnosis and treatment of medical disorders and does not collect or solicit information from individuals of the general public; however, the system components, applications, or electronic collections may require an OMB Control Number per DoDM 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).